JUN 2 9 2006

Special 510(k) Summary
for
VERIFY® SYSTEM 1 Biological Monitoring Kit 24 HR RIT

1. SPONSOR

STERIS CORPORATION
5960 Heisley Rd.
Mentor, OH 44060

Contact: Richard Bancroft (Albert Browne Ltd.)
Telephone: 0116 276 8636 (Albert Browne Ltd.)

Date Prepared: June 19, 2006

2. DEVICE NAME

Proprietary Name: VERIFY® SYSTEM 1 Biological Monitoring Kit 24 HR RIT
Common/Usual Name: Biological indicator
Classification Name: Biological sterilization process indicators

3. PREDICATE DEVICE

- VERIFY® SYSTEM 1 Biological Monitoring Kit (K053249)

4. DEVICE DESCRIPTION

The proposed VERIFY® SYSTEM 1 Biological Monitoring Kit 24 HR RIT is identical in components, design, and performance specifications to the predicate VERIFY® SYSTEM 1 Biological Monitoring Kit described in K053249. The only modification made to the parent device to produce the VERIFY® SYSTEM 1 Biological Monitoring Kit 24 HR RIT is a change in the growth media to support an 24 hour RIT (Reduced Incubation Time).

5. INTENDED USE

The VERIFY® SYSTEM 1 Biological Monitoring Kit 24 HR RIT is intended for use with STERIS SYSTEM 1®, a liquid chemical sterilization system. The VERIFY® Biological Monitoring Kit 24 HR RIT provides independent confirmation that sterilization conditions were achieved during the STERIS SYSTEM 1® processing cycle.

6. SUBSTANTIAL EQUIVALENCE

Comparison Chart for Determination of Substantial Equivalence

Item for Comparison	VERIFY® SYSTEM 1 Biological Monitoring Kit K053249	VERIFY® SYSTEM 1 Biological Monitoring Kit 24 HR RIT proposed
Intended Use	Intended for use with STERIS SYSTEM 1®, providing independent confirmation that sterilization conditions were achieved during the STERIS SYSTEM 1® processing cycle.	
Organism	*Geobacillus stearothermophilus*	Same
Components and Accessories	• Indicator strips • Vial of growth medium • Transfer clip	Same
Viable Spore Population	10^5 cfu/strip	Same
Resistance characteristics		
• D-value	15-36 s @ 1000 ppm PAA; 50 ± 1°C	Same
• Survival/Kill Window	≥41 s / ≤360s @ 1000 ppm PAA; 50 ± 1°C	Same
Culture Conditions	• Growth medium • Incubation temp 55-59°C • RIT: 48 hours	• Growth medium[+] • Incubation temp 55-59°C • RIT: 24 hours
Carrier Materials	paper strip	Same
Storage Temperature	2-24 °C	Same
Shelf Life	12 months	6 months

[+] The growth medium composition was adjusted in order to achieve a 24 HR RIT (Reduced Incubation Time)

7. PERFORMANCE TESTING

The VERIFY® SYSTEM 1 Biological Monitoring Kit 24 HR RIT is in compliance with the following voluntary standards:

- ANSI/AAMI ST59:1999, "Sterilization of health care products – Biological indicators – Part 1: General requirements"
- United States Pharmacopoeia 28 [1035] "Biological Indicators for Sterilization"

Testing was performed to support an RIT of 24 hours for the proposed VERIFY® SYSTEM 1 Biological Monitoring Kit 24 HR RIT. The results demonstrate that the VERIFY® SYSTEM 1 Biological Monitoring Kit 24 HR RIT can reliably be used for the monitoring of the STERIS SYSTEM 1® and confirms that the VERIFY® SYSTEM 1 Biological Monitoring Kit 24 HR RIT meets the current requirements of FDA guidance and relevant industry standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2006

STERIS Corporation
C/O Dr. Cynthia J.M. Nolte
Senior Staff Consultant
Medical Device Consultant, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K060568
Trade/Device Name: VERIFY® SYSTEM 1 Biological Monitoring Kit 24 HR RIT
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: June 19, 2006
Received: June 20, 2006

Dear Dr. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: VERIFY® SYSTEM 1 Biological Monitoring Kit 24 HR RIT

Indications for Use:

The VERIFY® SYSTEM 1 Biological Monitoring Kit 24 HR RIT is intended for use with STERIS SYSTEM 1®, a liquid chemical sterilization system. The VERIFY® SYSTEM 1 Biological Monitoring Kit 24 HR RIT provides independent confirmation that sterilization conditions were achieved during the STERIS SYSTEM 1® processing cycle.

Prescription Use _____ AND/OR Over-The-Counter Use x
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K060568